

# PATENT SPECIFICATION

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## DRAWINGS ATTACHED

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## (54) DEVICE FOR COLLECTING BIOCURRENTS OF THE FOETAL HEART

(71) We, SPITALUL CLINIC DE OBSTETRICĂ SI GINECOLOGIE POLIZU, a Body Corporate duly established under the laws of Roumania, of Polizu strada, 38-52, Bucharest, Roumania, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention relates to a device for collecting bio-electric currents of the foetal heart by the endo-uterine way during labour and expulsion.

It is known to record the endo-uterine foetal electrocardiogram (ECG) during the period of delivery by using, for the purpose of collecting bio-electric currents, two cups made of dielectric material into which are introduced two silver electrodes, which electrodes are connected to the electrocardiograph by conductors each of which is insulated in a polyethylene tube. The polyethylene tubes also, at the same time, connect the two cups with a vacuum source. The two cups containing the silver electrodes are applied to both sides of the head of the foetus and remain fixed to the foetus by reason of the reduced pressure in the cups.

In this way it is possible to obtain a perfectly outlined ECG, devoid of the maternal ECG waves.

The disadvantage of the above-mentioned device derives from the necessity of applying the two cups to the head of the foetus in conditions of rather low dilatation of the cervix uteri (according to indications in the literature, from 1/2-2 finger breadths), the manoeuvre being exceedingly difficult.

It is also known to adapt a vacuum extractor by fitting in its dome the two electrodes required for collecting bio-electric currents. This collecting device, which can be applied to the head of the foetus, has the disadvantage of being usable only at the time of expulsion, ruling out any possible employment in the preceding periods, when in many cases

however, it is necessary to know accurately the vital conditions of the foetus.

The present invention provides a device for collecting bio-electric currents of the foetal heart which comprises a cupping glass made of dielectric material, a tube fastened at one end to the cupping glass, and a metallic electrode having a head and a stem portion and mounted in the cupping glass, the stem portion having a hollow interior which communicates on the one hand with the interior of the tube and on the other hand with the interior of the cupping glass by way of at least one hole in the wall of the stem portion, and the free end of the tube being connected to a suction bulb and the free end of the tube being provided with a terminal for connection of the device to an electrocardiograph, which terminal is electrically connected to the electrode.

There now follows one example of the construction and employment of the device according to the invention, reference being had to the accompanying drawings which represents a longitudinal section through the device.

The device according to the invention consists of a cupping glass 1, manufactured of dielectric material, wherein is fitted a metallic tube 2 provided, at the end which is fastened in the cupping glass, with a threaded portion  $\alpha$  to which is screwed a collecting electrode 3 having the general form of a mushroom. The threaded part or stem of the collecting electrode 3 is prolonged in such a way as to provide between the dome of the electrode 3 and the end of the metallic tube 2, an empty space  $s$  which communicates with the suction space  $v$  of the cupping glass 1, by way of lateral holes  $o$ , bored in the stem of the collecting electrode 3. The metallic tube 2 fulfils the role of conductor of the bio-currents collected by the electrode 3 and is provided, at its end opposite to that fixed in the cupping glass 1, and in a convenient position, with a terminal 4 attached by welding. Moreover, between the cupping glass 1

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and the terminal 4, the tube 1 is insulated by a layer of dielectric material 5. In this way, bi-electric current collected by the electrode 3 can be transmitted through a conductor (not illustrated), which serves as a link between the terminal 4 and the input of the electrocardiograph. The attachment of the collecting electrode 3 to the foetus is achieved with the help of the cupping glass 1, which after being put in contact with the head of the foetus by palpation, will be sufficiently attached by evacuation of the space  $\tau$ , carried out by appropriate manipulation of a suction bulb 6, connected to the tube 2 by an flexible connecting tube 7. By manipulation of the suction bulb 6, the air is sucked from the space  $\sigma$  through the holes  $\phi$  and tube 2 and in this manner the cupping glass 1 is sucked onto a portion of the skin on the head of the foetus, which in this way will come into contact with the mushroom head of the electrode 3. Thus permanent contact between the subject (foetus) and the electrocardiograph is established.

Experiments conducted so far have shown that for maintaining permanent contact between the collecting electrode 3 and the head of the foetus it is sufficient to operate the suction bulb 6 at relatively long time intervals, which when the suction bulb is operating normally and the cupping glass 1 is correctly applied, is about every 15 minutes or even longer.

The diameter of the cupping glass 1 should be in each case less than the dilatation of the cervix uteri, even when the foetal skull is situated high, and consequently the diameter of the cupping glass 1 is preferably as close as possible to 2 cm, and may be reduced even to 1 cm.

As has been mentioned above, by the use of the device according to the invention, bio-electric currents of the foetal heart can be collected by the endo-uterine way all through the period of labour and expulsion, but is also possible to collect these currents even outside labour when the viability of the foetus has become doubtful. In this case, however, the device should not be employed before the seventh month or beneath the minimum foetal weight consistent with viability of the foetus, irrespective of whether the amniotic membranes is already torn or whether it is necessary to artificially rupture the membranes.

Whenever a single collecting electrode 3 is fitted in the cupping glass 1 the foetal ECG is simultaneously recorded with maternal ECG, but the waves of the two subjects

are completely differentiated and easily visible.

The cupping glass 1 can be fitted with two electrodes, but in the latter case the tube 2 must be manufactured from a dielectric material and the conduction of the bio-electric currents collected by two electrodes performed by separate and insulated conductors, which pass from the electrodes in the cupping glass 1, through the tube to separate terminals fitted accordingly to the end of the tube 2 opposite to that fixed in the cupping glass 1.

The device according to the invention has the advantage of being capable of investigating and following the conditions of viability of the foetus not only during labour and expulsion but also in cases where the viability of foetus is uncertain, but in the latter case only as specified above, namely only in the seventh month and in conditions of foetal weight corresponding to viability.

#### WHAT WE CLAIM IS:—

1. Device for collecting bio-electric currents of the foetal heart which comprises a cupping glass made of dielectric material, a tube fastened at one end to the cupping glass, and a metallic electrode having a head and a stem portion and mounted in the cupping glass, the stem portion having a hollow interior which communicates on the one hand with the interior of the tube and on the other hand with the interior of the cupping glass by way of at least one hole in the wall of the stem portion, and the free end of the tube being connected to a suction bulb and the free end of the tube being provided with a terminal for connection of the device to an electrocardiograph, which terminal is electrically connected to the electrode.

2. Device according to claim 1 in which the tube is metallic and is covered on its exterior by a sleeve of dielectric material, the terminal being mounted in electrically conductive manner on the tube and the stem portion of the electrode being mounted directly on the end of the tube.

3. Device according to claim 2 in which the tube is attached to the stem portion of the electrode by engagement of respective threaded portions thereof.

4. Device according to claim 2 or 3 including an flexible tube which interconnects the free end of the metal tube and the suction bulb.

5. Device according to claim 1, in which the tube is of dielectric material and carries two terminals which are connected by separate conductors passing down the tube to two electrodes mounted in the cupping glass.

6. Device for collecting bio-electric currents of the foetal heart substantially as described with reference to the accompanying drawing.

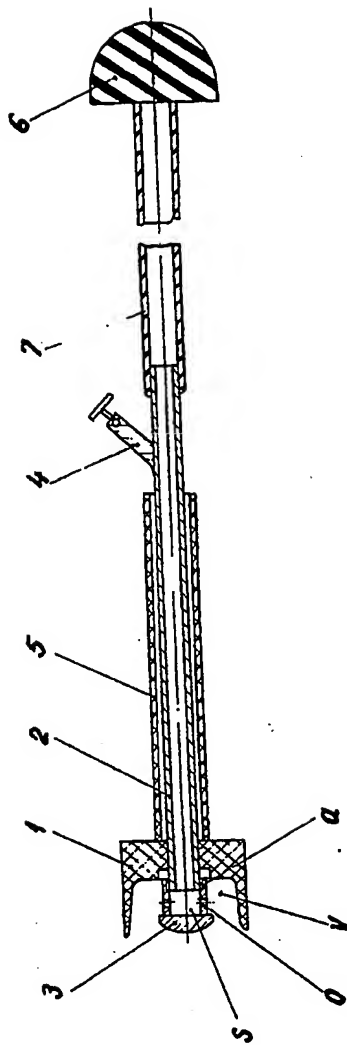
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1260919 COMPLETE SPECIFICATION

1 SHEET

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